510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k053138

B. Purpose for Submission:
New device

C. Measurand:
Human chorionic gonadotropin (hCG)

D. Type of Test:
Qualitative, lateral flow immunoassay, Over-the-Counter (OTC)

E. Applicant:
Ani Biotech Oy

F. Proprietary and Established Names:
MySet™ Pregnancy Test

G. Regulatory Information:

1. Regulation section:
   21 CFR section 862.1155 Human chorionic gonadotropin test system

2. Classification:
   Class II

3. Product code:
   LCX

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use.

2. Indication(s) for use:
   The MySet Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine, for the early detection of pregnancy. For Over-the-Counter Use.

3. Special conditions for use statement(s):
For Over-the-Counter Use

4. Special instrument requirements:
None

I. Device Description:
The product is supplied as either a single test kit or a double test kit. Each test is individually packaged in a sealed foil pouch. The pouch contains the test cassette, the sampling stick and a desiccant to control humidity.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Stanbio True® 20 One-Step Pregnancy Test

2. Predicate 510(k) number(s):
k980531

3. Comparison with predicate:

Similarities		
Item	k053138 MySet	Predicate
Analyte measured	Same	Qualitative detection of hCG
Sample type	Same	Urine
Sensitivity	25 mIU/mL	20 mIU/mL

Differences		
Item	k053138	Predicate
Intended Use	Over-the-Counter	Professional Use

K. Standard/Guidance Document Referenced (if applicable):
Not applicable

L. Test Principle:
The test employs a combination of monoclonal-dye conjugate and monoclonal solid-phase antibody to selectively bind to human chorionic gonadotropin in urine. The sampling stick is used to collect mid-stream urine for about 5 seconds. As the urine sample flows through the absorbent portion of the device, the antibody-dye conjugate binds to the hCG in the urine forming an antibody-antigen complex. The complex then binds to the anti-hCG antibody in the test window. If the concentration of hCG in the urine is 25 mIU/mL or greater, a red line appears. In the absence of hCG or

hCG concentrations less than 25 mIU/mL, a line will not appear in the test window. Unbound monoclonal dye-conjugate binds to the reagents in the control window, producing a red line. This indicates that the test is functioning properly and that a sufficient amount of urine has been applied. The result is read after five minutes and users are cautioned not to read a negative result after 10 minutes.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
See detection limit

b. Linearity/assay reportable range:
Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The assay was standardized using the hCG WHO 3rd International Standard 75/537.

d. Detection limit:
A male urine pool was spiked with hCG (WHO 3rd IS) at concentrations of 0, 2, 6.25, 12.5, 25, 50 and 100 mIU/mL and tested. For each level 12 tests were run in parallel. The test samples at 0, 2, 6.25, and 12.5 mIU/mL were negative while the 25, 50, and 100 mIU/mL levels were positive. A 25 mIU/mL sensitivity is claimed.

e. Analytical specificity:
Luteinizing hormone (600 mIU/mL), follicle stimulating hormone (2000 mIU/ml) and thyroid stimulating hormone (1000 µIU/mL) were added to hCG negative and hCG positive (25 mIU/mL hCG added) spiked samples. A male urine pool was used to prepare the samples. Each hormone spiked into hCG negative urine gave negative results in the assay (n=10). Each hormone spiked into the urine containing 25 mIU/mL hCG all gave positive results (n=10).

Common prescription and OTC drugs, as well as hemoglobin, protein, bilirubin and glucose were tested with the device at specified concentrations. The potentially interfering substances were tested at concentrations known to be in excess of what would be excreted after 8 hours by the human kidney. The substances were spiked into male urine pools containing either 0 mIU/mL hCG or 25 mIU/mL hCG. None of the substances caused interference.

The effect of varying pH on test results was examined. The pH of a male urine pool was adjusted to pH 8.36, 5.20, 4.23, and 2.88. Then, a portion of each urine pool was spiked with 25 mIU/mL hCG. The urine pools at each pH, with and without hCG were tested with the device. The urines with 25 mIU/mL hCG were

all positive (n=10) while the urines without hCG were all negative (n=10).

f. Assay cut-off:
See (d) Detection Limit

2. Comparison studies:

a. Method comparison with predicate device:
Urine specimens (n=100) were obtained at a clinic from women suspecting pregnancy. Specimens were randomly collected at different times of the day. The specimens were tested by a laboratory professional using the MySet device as well as the reference method, the Stanbio Laboratory True 20 One-Step pregnancy test. There was 100% agreement between the methods.

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):
Consumer studies were performed to determine if the device could successfully be used by a lay person using only the provided written instructions. The 100 women described in section 2(a) were asked to perform the pregnancy test and the results were compared to the results obtained by a laboratory professional. The untrained users were demographically diverse, with respect to age and education. There was 100% agreement between the untrained user and the laboratory professional results.

The study participants were asked to complete a questionnaire to gauge the readability of the written instructions. All participants understood the instructions and the importance of the control line when performing the test.

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
The expected values are based on literature. Healthy males and non-pregnant females should not have detectable hCG in urine by this method.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports substantial equivalence decision.